

INFORMED CONSENT CONSIDERATION FOR EMBRYO GENOME EDITING STUDIES

Introduction

On February 4, 2016, CIRM convened the Scientific and Medical Accountability Standards Working Group (SWG) for a workshop on Human Gene Editing. The aim of the workshop was to review research directions in California and CIRM policies associated with gene editing of human germ cells and blastocysts. On March 23, 2016, CIRM published Draft Recommendations based on the workshop deliberations. ²

During the workshop the scientific value of *in vitro* research involving human blastocysts was described.³ Basic research directions include studies to improve:

- Reproductive outcomes for infertility treatment
- Understanding of human development
- Stem cells, derived cell lines and regenerative medicine
- The fidelity of CRISPR in human embryos

In vitro research involving human blastocysts typically occurs by utilizing banked blastocysts that have been donated for research purposes. The SWG emphasized that informed consent for blastocyst donation should indicate that donated blastocysts may be genetically modified. The current CIRM policy requires that blastocyst donors be informed that "derived cells or cell products may be used in research involving genetic manipulation."

To support the broadest use of donated materials in research, CIRM proposes modifying this policy to recommend embryo donors be informed:

"donated embryos [blastocysts], derived cells or cell products may be used in research involving genetic manipulation."

If you have comments or questions regarding this recommendation, please contact Geoffrey Lomax Dr.PH. glomax@cirm.ca.gov. The comment deadline is August 31, 2016.

¹ https://www.cirm.ca.gov/agendas/01122016/standards-working-group-meeting

https://www.cirm.ca.gov/sites/default/files/files/board_meetings/Genome Editing Workshop Draft Summary 3_22_16_Revised_6_8_2016.pdf

³ https://www.cirm.ca.gov/sites/default/files/files/agenda/transcripts/StdsWkgGroup-2-4-16%20Transcript.pdf p 136.